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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,932	01/09/2006	Mark G. Erlander	14255-052US1	7099

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EXAMINER	
CHUNDURU, SURYAPRABHA	

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,932	ERLANDER ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Applicants' response to the office action field on February 20, 2008 has been considered and acknowledged.

Status of the application

2. Currently claims 2-28 are pending. Claim 1 is cancelled. Applicants' arguments and the amendment have been fully considered and deemed persuasive for the reasons that follow.

3. The Information Disclosure Statement filed on March 20, 2008 has been considered and acknowledged.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 2-7, 9-23, 25-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baugh et al. (Nucleic Acids Res., Vol. 29, No. 5e29 1-9, 2001) in view of Smith et al. (USPN. 6,027,945).

Baugh et al. teach a method of claim 2, 20, 38, for producing amplified RNA (aRNA) comprising

(a) reverse transcribing an RNA template using a promoter-primer complex and an RNA dependent DNA polymerase (reverse transcriptase enzyme) to produce a first strand cDNA (see page e29, 2, col. 1, paragraph 2, col. 2, paragraph1);

(b) treating the reverse transcription product with RNAse H enzymatic activity (see page e29 2, col. 2, paragraph1);

(c) producing a second strand cDNA complementary to said first strand cDNA using a DNA dependent polymerase, in the presence of random primers to prime the synthesis of said second strand cDNA (see page e29 2, col. 2, paragraph1);

(d) producing amplified RNA from the eluted double stranded cDNA by invitro transcription using a DNA dependent RNA polymerase which initiates transcription from the primer of said promoter-primer complex (see e29 2, col. 2, paragraph1);

wherein the product produced after c), after d) or both, is purified by contacting said product with a solid phase which binds nucleic acids followed by eluting bound nucleic acids from the solid phase (see e29 2, col.1, paragraph 2, col. 2, paragraph 2 indicating that the product produced after c) and d) are purified, especially the product produced after d) is contacted with solid phase (paramagnetic bead).

With regard to claim 2, Baugh et al. teach said first and second strand cDNA synthesis is carried out in a reaction time less than 45 minutes (see page e29 2, col. 2, paragraph 1, indicating 40 min at 42^0 C and 10 min at 50^0 C).

With regard to claims 3-4, Baugh et al. teach that the RNA template comprises mRNA and the template is derived from cellular mRNA preparation (total RNA sample) (see page e29 2, col. 1, paragraph 1-2).

With regard to claims 5-6, Baugh et al. teach that the first primer comprises oligo d(T) comprising at least 8 dT (see page e29 2, col. 1, paragraph 3).

With regard to claim 7, 23, Baugh et al. that the random primers are six nucleotides (see page e29 2, col. 2, paragraph 1).

With regard to claims 22, 25-27, Baugh et al. teach that the promoter primer comprises T7 or T3 promoter sequence (see page e29 3, col. 1, paragraph 2 under results section).

However Baugh et al. did not specifically teach elution of nucleic acids in a volume of less than 50ul.teach that the solid support comprising silica particles or diatomaceous earth, wetting capacity, elution by centrifugation.

Smith et al. teach a method of isolating biological target materials (nucleic acids) using a silica magnetic solid particles, wetting capacity equal to elution volume and elution by centrifugation wherein Smith et al. teach that the method comprises providing a solid phase (silica particles) and combining the solid phase with the biological material and isolating the target-solid phase complex and recovering the biological material from the solid phase (see col. 5, line 1-30).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of producing aRNA as taught by Baugh et al. with a step of purifying the nucleic acid as taught by Smith et al. to achieve expected advantage of developing a sensitive and enhanced method of producing aRNA. An ordinary practitioner would have been motivated to combine the teaching of Baugh et al. with the step of isolating the nucleic acids as taught by Smith et al. because one skilled in the art would have a reasonable expectation of success that the combination would result in purifying nucleic acids and improve the quality of the amplified nucleic acid because Smith et al. explicitly taught the silica particle packed column to purify nucleic acids for biological analysis (see col. 5, line 1-30) and such modification of the method would be considered as obvious over cited prior art. Further, as noted in *In re Aller*, 105 USPQ 233 at 235,More particularly, where the general conditions (suitable volume, incubation time)of a claim are disclosed in the prior art (Baugh and Smith et al), it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of hybridization conditions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

B. Claims 8, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baugh et al. (Nucleic Acids Res., Vol. 29, No. 5e29 1-9, 2001) as applied to claims 2, 20-23, 25-31, 38 above, and further in view of Gerdes et al. (US 6,872,527).

Baugh et al. in view of Smith et al. teach a method of producing amplified RNA as discussed above in section 4A.

However, neither Baugh et al. nor Smith et al. teach random primers of nine nucleotides or longer.

Gerdes et al. teach a method for genome wide amplification wherein the method utilizes 9-mer random primers to boost the amplification of entire or large fraction of the genome (see col. 26, line 23-64).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of producing aRNA as taught by Baugh et al. in view of Smith et al. with a step of random primers of nine nucleotides or longer in length as taught by Gerdes et al. to achieve expected advantage of developing a sensitive and enhanced method of producing aRNA. An ordinary practitioner would have been motivated to combine the teaching of Baugh et al. in view of Smith et al. with the step of random primers of nine nucleotides as taught by Gerdes et al. because one skilled in the art would have a reasonable expectation of success that the combination would result in amplifying a large fraction or entire nucleic acid of interest because Gerdes et al. explicitly taught the use of 9-mer random primers provide amplification of entire or a large fraction of the nucleic acid (see col. 26, line 56-64) and such modification of the method would be considered as obvious over cited prior art.

Response to arguments:

5. With regard to the objection to the abstract of the specification, Applicants' arguments were fully considered and found persuasive. The objection is withdrawn herein in view of the corrected version of the abstract submitted on 9/15/2004.

6. With regard to the rejection of claims 1, 3-7, 9-14 under 35 USC 102(e) as being anticipated by Cao et al., Applicant's arguments and amendment were fully considered and the rejection is with drawn in view of the amendment cancelling the independent claim 1.

7. With regard to the rejection of claims 2, 20-23, 25-31 under 35 USC 103(a) as being unpatentable over Cao et al. in view of Baugh et al., Applicant's arguments and amendment were fully considered and persuasive in-part. Applicants' arguments regarding Baugh et al. were found unpersuasive. The applicants' cited paragraphs disclosing 60 min incubation time is dependent on the concentration of starting RNA template, however, the same cited paragraph discloses less than 45 minutes incubation depending on the concentration of the starting template. Thus the incubation time varies based on the concentration used in the reaction. The rejection is with drawn in view of the amendment canceling claim 1.

8. With regard to the rejection of claims 8 and 24 under 35 USC 103(a) as being unpatentable over Cao et al. in view of Baugh et al., further in view of Gerdes, Applicant's arguments and amendment were fully considered and the rejection is with drawn in view of the amendment.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637